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10/550,748	11/09/2006	Claude Thibodeau	BRKP:004US/10509999	3767

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SCHMIDTMANN, BAHAR	
ART UNIT	**PAPER NUMBER**
1623	

NOTIFICATION DATE	DELIVERY MODE
11/12/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/550,748	THIBODEAU ET AL.	
	Examiner	Art Unit	
	BAHAR SCHMIDTMANN	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *10-22,26-28 and 31-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,23-25,29,30 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's Amendment and Remarks filed on 26 August 2010 in which claims 1-4 and 30 were amended to change the scope and breadth of the claims.

Claims 1-35 are pending in the current application. Claims 10-22, 26-28 and 31-34 remain withdrawn as being drawn to a non-elected invention. Claims 1-9, 23-25, 29, 30 and 35 are examined on the merits herein.

WITHDRAWN REJECTIONS

Applicant's amendment, filed 26 August 2010, with respect to the rejection of claims 2, 3 and 30 under 35 U.S.C. § 112, second paragraph, for indefiniteness, has been fully considered and is persuasive.

Claim 1 has been amended to recite "extruded" starch, which at least implies that the starch has been modified from its original state. This overcomes the indefiniteness of dependent clams 2 and 3.

Claim 30 has been amended to delete the limitations having a trademark.

The claims as amended more specifically claims the subject matter disclosed and supported in Applicant's Specification.

The rejections are hereby **withdrawn**.

MODIFIED REJECTIONS

The following are new ground(s) or modified rejections necessitated by Applicant's amendment, filed on 26 August, where the limitations in pending claims 1-4 and 30 as amended now have been changed. Specifically, independent claim 1 now requires that the starch be extruded. Therefore, rejections from the previous Office Action, dated 26 February 2010, have been modified and are listed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 23, 24, 25, 29, 30 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grossmann et al. (*Carbohydrate Polymers*, 45, 2000, 347-353, cited by Applicant in Information Disclosure Statement) as evidenced by

Sigma Aldrich (cited in PTO-892) in view of Hirsch et al. (*Cereal Chemistry*, 2002, cited by Applicant in Information Disclosure Statement) and in further view of Feil (EP 0900807, cited in previous Office Action).

Grossmann teaches cassava starch was cross-linked with sodium trimetaphosphate and sodium hydroxide and extruded and ground in an alpine mill to pass through an 80 mesh sieve (p.347-348, *2.2.Preparation of cross-linked starch*). According to Sigma Aldrich, an 80 mesh sieve results in particles having a 177 μm size. Grossman teaches the purpose of extrusion cooking is advantageous in that it results in lower cost, less waste and faster reaction time (p.347, *1. Introduction*, third paragraph). Grossman teaches the water absorption index increased when the sodium hydroxide concentration and temperature of the extrusion process were increased (p.349, *3.2. Water absorption, water solubility and clarity*, first paragraph). Grossman also teaches the cross-linking with the sodium trimetaphosphate increased water absorption (p.349, last paragraph to p.350, first paragraph).

Grossman does not expressly disclose the cassava having an amylopectin content of 90% (w/w) or that it is waxy (instant claim 1 and 4). Grossman does not expressly disclose a free swell capacity and centrifuge retention capacity (instant claim 35).

Hirsch et al. teaches that waxy starches, which are made up almost entirely of amylopectin, are used as the starting material for producing cross-linked starch since the amylose in non-waxy starch retrogrades on cooling and forms an irreversible gel (p.102, second paragraph). Hirsch et al. teaches that amylopectin allows for cross-

linking agents to bind on neighboring anhydroglucose units, which prevents the granules from fully swelling ultimately disintegrating (p.102, second paragraph). Hirsch et al. expressly suggests the use of waxy maize starch for producing cross-linked stach (p.102, second paragraph). Hirsch et al. teaches that the covalent crosslinking network makes the starch granules tolerant to pH extremes and high shear processes (p.102, second paragraph).

Feil teaches the water-absorbing cross-linked starch can be used as sanitary product, medical aid such as bandages, coating for drugs to control the release rate by degradation of the hydrogel, humidity controlling agents for agriculture and horticulture, encapsulant for colorants, fragrances, perfumes, fertilizers and nutrients, pet litter and gel filtration columns (column 4, lines 48-58 and column 5, lines 1-5). Feil teaches water-absorbing polymers prepared from carboxymethyl cellulose or carboxymethyl starch (column 2, lines 21-31). Feil teaches any native granular starch, physically, enzymatically or chemically modified starch may be used (column 2, lines 53-58 and column 3, lines 1-12). Feil teaches the particle size is determined by mixing energy parameter, suggesting the size can be modified by altering mixing energy (column 4, lines 16-20). Feil teaches starch or the starch material cross-linked with sodium trimetaphosphate wherein the particle size is 300-400 μm (column 5, example 1, lines 18-20 and claims 1 and 4). Feil teaches also teaches cross-linked starch material wherein the particle sizes range from 0.2 to 10 micron (column 7, lines 11-13).

It would have been obvious at the time the invention was made to have a particulate absorbent material comprising waxy starch that is cross-linked or self-

entangled and composed mainly of amylopectin, wherein fiber or carboxymethyl cellulose is used as a co-absorbent.

Based on the teachings of the MPEP and KSR cited in the previous Office Action, by employing the rationale in (A) combining prior art elements according to known methods to yield predictable results, (B) simple substitution of one known element for another to obtain predictable results and (G) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention; one having ordinary skill in the art would have been motivated to have a particulate absorbent material comprising waxy cassava starch that is cross-linked or self-entangled and composed mainly of amylopectin, wherein fiber or carboxymethyl cellulose is used as a co-absorbent.

From the teaching of Hirsch et al., one having ordinary skill in the art would have been motivated to substitute the cassava starch material that is cross-linked and extruded in the Grossman reference because waxy starch is known to be composed mainly of amylopectin. According to Hirsch et al., the amylopectin and cross-linking modification allows for the formation of starch granules that can absorb a high amount of water without collapsing or disintegrating the starch network. Although the Hirsch et al. reference does not expressly disclose the percent weight of amylopectin, this is an inherent property of the waxy starches.

From the teaching of Fiel, it is known that cross-linked starch materials, such as starch cross-linked with sodium trimetaphosphate, can be used in drug release

formulations (i.e. active agent) as well as absorbent materials. As a result, one having ordinary skill would be motivated to use the waxy casssava starch that mainly contains amylopectin in lieu of the starch derivatives taught by Fiel, i.e. starch cross-linked with sodium trimetaphosphate and combine the starch with a co-absorbent such as carboxymethyl cellulose. Additionally, the Fiel reference teaches the water-absorbing starch material can be used in products that are well known by one of ordinary skill in the art to be formed from fibers, like sanitary products such as sanitary napkins and medical aids such as bandages and swathes. Therefore, while Fiel does not expressly teach using a co-absorbent material, Fiel does suggest to one of ordinary skill in the art that the water-absorbing starch material can be combined with fiber containing products, which is inherently a co-absorbent material.

Moreover, since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), see MPEP 2112. Therefore, the cassava starch disclosed by Grossmann et al. is assumed to be self-entangled (or chain entangled), have a free swell capacity of at least 13 g/g and a centrifuge retention capacity of at least 10 g/g.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teaching of the prior art.

Response to Arguments

Applicant's amendments are directed towards an extruded starch network. As such, the above 103 rejection has been modified.

Applicant's arguments with respect to claims 1-9, 23, 24, 25, 29, 30 and 35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

In view of the rejections to the pending claims set forth above, no claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. BAHAR SCHMIDTMANN whose telephone number is 571-270-1326. The examiner can normally be reached on Mon-Thurs 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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